NOTICE OF INTENT

Department of Health and Hospitals
Office of Behavioral Health

Drug Regulations
Opioid Antagonist Administration
(LAC 49:I.1199)

The Department of Health and Hospitals, Office of Behavioral Health proposes to adopt LAC 49:I.Chapter 11, 1199 governing opioid antagonist administration and training as authorized by R.S. 40:978.2. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq. Act 192 of the 2015 Regular Session of the Louisiana Legislature provides for the creation of R.S. 40:978.2, which requires the Department of Health and Hospitals, Office of Behavioral Health to adopt provisions governing the best practices, training, storage, administration, and emergency follow-up procedures for opioid antagonists administered to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose.

Title 49
PUBLIC HEALTH—FOOD AND DRUGS
Part I. Food, Drugs, and Cosmetics
Chapter 11. Drug Regulations
§1199. Opioid Antagonist Administration and Training

A. Purpose and Applicability

1. Pursuant to R.S. 40:978.2, to protect public health and safety, the Department of Health and Hospitals sets forth the following training and monitoring requirements for a licensed medical practitioner who prescribes, dispenses, or administers naloxone or another opioid antagonist to a person reasonably believed to be undergoing an opioid-related drug overdose.

2. Training and monitoring requirements of this Rule shall apply to licensed medical practitioners when dispensing or distributing opioid antagonists to third parties who will be administering the medication. Training shall include how to recognize signs of overdose indicating when it is appropriate to utilize naloxone or another opioid antagonist, standards for storage and administration of the medication, and instructions for emergency follow-up procedures.

3. First responders as defined in R.S. 40:978.1 are exempt from the training requirements as detailed in this Rule.

4. Prescribers are strongly encouraged to co-prescribe naloxone or another opioid antagonist once in a given year to persons receiving opioid therapy for greater than 14 days.

B. Definitions

Department—the Department of Health and Hospitals.

Licensed Medical Practitioner—a physician or other healthcare practitioner licensed, certified, registered, or otherwise authorized to perform specified healthcare services consistent with state law.

Opioid Antagonist—agents such as naloxone that have high affinity and bind to opiate receptors but do not activate these receptors. This effectively blocks the receptor, preventing the body from responding to opioids and endorphins. These drugs block the effects of externally administered opioids.

Opioid-Related Overdose—a condition including extreme physical illness, decreased level of consciousness, respiratory depression, coma, or the ceasing of respiratory or circulatory function resulting from the consumption or use of an opioid, or another substance with which an opioid was combined.

SAMHSA—the Substance Abuse and Mental Health Services Administration.

Toolkit—the SAMHSA Opioid Overdose Toolkit. Reference available online through SAMHSA's website.

C. Training Requirements

1. At minimum, licensed medical practitioners shall provide the following information and training regarding signs of overdose when prescribing, distributing, or dispensing an opioid antagonist:

a. Signs of overdose, which often results in death if not treated, include:

i. Face is extremely pale and/or clammy to the touch.

ii. Body is limp.

iii. Fingernails or lips have a blue or purple cast.

iv. The patient is vomiting or making gurgling noises.

v. He or she cannot be awakened from sleep or is unable to speak.

vi. Breathing is very slow or stopped.

vii. Heartbeat is very slow or stopped.

b. Signs of overmedication, which may progress to overdose, include:

i. Unusual sleepiness or drowsiness;

ii. Mental confusion, slurred speech, intoxicated behavior;

iii. Slow or shallow breathing;

iv. Pinpoint pupils;

v. Slow heartbeat, low blood pressure; and

vi. Difficulty waking the person from sleep.

c. For additional guidance and information, please reference the most recent version of the SAMHSA Opioid Overdose Toolkit.

2. At minimum, licensed medical practitioners shall provide the following information and training regarding storage and administration when prescribing, distributing, or dispensing an opioid antagonist:

a. Instructions on storage of the opioid antagonist in accordance with the manufacturer instructions.

b. Instructions on administration of the opioid antagonist in accordance with the instructions printed on or distributed with the device by the manufacturer.

3. At minimum, licensed medical practitioners shall provide the following information and training regarding emergency and follow-up procedures when dispensing or prescribing an opioid antagonist:

a. Prior to administration, the person administering the opioid antagonist shall immediately call 9-1-1 for emergency medical services if medical assistance has not yet been sought or is not yet present.

b. After calling for emergency services and administering the opioid antagonist, emergency follow-up procedures shall be conducted in accordance with the guidelines set forth in the SAMHSA Opioid Overdose Toolkit.

c. Upon stabilization by emergency medical services, the treating practitioner shall refer the patient to and offer information regarding substance use treatment services.

G. Monitoring

1. Pharmacists dispensing naloxone or other opioid antagonists shall maintain a record of persons receiving training prior to the dispensing of the medication as per this Chapter, including recipient's acknowledgement by signature. Records shall be retained in accordance with the prescriber's scope of practice requirements.

2. Other licensed medical practitioners prescribing or distributing naloxone or other opioid antagonists shall maintain a record of persons receiving training as per this Chapter including recipient's acknowledgement by signature. Training shall be completed prior to prescribing or distributing the medication. Records shall be retained in accordance with the practitioner's scope of practice requirements.

3. Training records will be subject to monitoring and audit by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:978.2.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Behavioral Health, LR 41:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have a positive impact on family functioning, stability or autonomy as described in R.S. 49:972 by assuring training at no additional cost and the safe administration of opioid antagonists during potential overdose situations, thereby saving lives and preserving the family unit. Subsequent follow-up procedures will require families to be linked to local substance use treatment options that will also serve to maintain the family unit.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973. Training will be completed upon dispensing or distribution of the opioid antagonist at no additional cost to the recipient.

Small Business Statement

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, the economic impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will not have an adverse impact on small businesses, as described in R.S. 49:965.2 et seq. Record keeping shall include pharmacies and licensed medical practitioners dispensing or distributing opioid antagonists maintaining files that recipients have been trained according to the proposed Rule and are subject to audit by the department.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have a minimal impact on providers as described in HCR 170. Staffing and costs are not anticipated to be impacted, however, minor recordkeeping requirements may create a minimal workload increase to providers.

Public Comments

Interested persons may submit written comments to Jen Katzman, Office of Behavioral Health, P.O. Box 4049, Baton Rouge, LA 70821 or by email to jennifer.katzman@la.gov. Jen Katzman is responsible for responding to inquiries regarding this proposed Rule. The deadline for receipt of all written comments is 4:30 p.m. on October 12, 2015.

Kathy H. Kliebert
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Drug Regulations
Opioid Antagonist Administration

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that $1,704 in state general funds will be expended in FY 15-16 for the state's administrative expense for promulgation of this proposed rule and the final rule. The proposed rule implements the requirements of Act 192 of the 2015 Regular Session to set forth best practice training requirements by licensed medical practitioners other than first responders, on distribution, storage, administration, and emergency follow-up procedures for opioid antagonists administered to individuals who are undergoing or who are believed to be undergoiung an opioid-related overdose. There are no anticipated programmatic costs resulting from implementation of training requirements detailed in the proposed rule.

For Local Governing Entities (LGEs) that opt to distribute naloxone or other opioid antagonists to clients, they will have to maintain a training log of persons receiving the medication. It is anticipated that this function can be absorbed within current LGE workload and staff.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There is no anticipated impact on revenue collections to state or local governing entities as a result of the proposed rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

Licensed medical practitioners may encounter a minimal workload increase to provide training and maintain a record that recipients of the medication have been trained according to the Rule, which shall be available for DHH audit upon request. The practitioner shall retain this log with any other records it is required to maintain in accordance with their scope of practice.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There is no anticipated impact on competition and employment resulting from the proposed rule.

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